

AMENDED IN ASSEMBLY APRIL 14, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL

No. 512

Introduced by Assembly Member Richman

February 16, 2005

An act to amend Sections 1310 and 1320 of the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 512, as amended, Richman. Clinical laboratories.

Under existing law, the State Department of Health Services licenses and regulates clinical laboratories and clinical laboratory personnel. A violation of these provisions is a misdemeanor. Under existing law, the department may deny, suspend, or revoke a license or registration for specified reasons.

This bill would also authorize the department to deny, suspend, or revoke a license or registration for failure to comply with specified infectious disease reporting requirements.

Existing law authorizes the department to impose specified penalties in lieu of, or in addition to, revocation or suspension of a license or registration.

This bill would also authorize the department to impose civil monetary penalties for failure to comply with specified infectious disease reporting requirements.

Because a violation of the bill would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1310 of the Business and Professions
2 Code is amended to read:

3 1310. If the department determines that a laboratory that has
4 been issued a license or registration under this chapter, except for
5 a laboratory only performing tests or examinations classified as
6 waived under CLIA, no longer substantially meets the
7 requirements of this chapter or the regulations adopted
8 thereunder, the department, in lieu of, or in addition to,
9 revocation or suspension of the license or registration under
10 Section 1320 or 1323, may impose any of the following:

11 (a) Directed plans of correction, as defined under CLIA.

12 (b) Civil money penalties in an amount ranging from fifty
13 dollars (\$50) to three thousand dollars (\$3,000) per day of
14 noncompliance, or per violation, for a condition level deficiency
15 that does not pose immediate jeopardy, to an amount ranging
16 from three thousand fifty dollars (\$3,050) to ten thousand dollars
17 (\$10,000) per day of noncompliance, or per violation, for a
18 condition level deficiency that poses immediate jeopardy, but
19 only after notice and an opportunity to respond in accordance
20 with Section 100171 of the Health and Safety Code, and
21 consideration of facts enumerated in CLIA in Section 493.1834
22 of Title 42 of the Code of Federal Regulations.

23 ~~(c) Onsite monitoring, as defined under CLIA, and payment~~
24 ~~for the costs of onsite monitoring.~~

25 ~~(d) Any combination of the actions described in subdivisions~~
26 ~~(a), (b), and (c).~~

27 ~~(e)~~

28 (c) Civil money penalties in an amount ranging from fifty
29 dollars (\$50) to three thousand dollars (\$3,000) per day of
30 noncompliance, or per violation for a violation of subdivision (t)
31 of Section 1320, for failure to report a finding of infectious
32 disease, but only after notice and an opportunity to respond in
33 accordance with Section 100171 of the Health and Safety Code,

1 and for condition-level deficiencies, after considering factors
2 listed in subdivision (b) of Section 1067.5 of Title 17 of the
3 California Code of Regulations.

4 *(d) Onsite monitoring, as defined under CLIA, and payment*
5 *for the costs of onsite monitoring.*

6 *(e) Any combination of the actions described in subdivisions*
7 *(a), (b), (c), and (d).*

8 SEC. 2. Section 1320 of the Business and Professions Code is
9 amended to read:

10 1320. The department may deny, suspend, or revoke any
11 license or registration issued under this chapter for any of the
12 following reasons:

13 (a) Conduct involving moral turpitude or dishonest reporting
14 of tests.

15 (b) Violation by the applicant, licensee, or registrant of this
16 chapter or any rule or regulation adopted pursuant thereto.

17 (c) Aiding, abetting, or permitting the violation of this chapter,
18 the rules or regulations adopted under this chapter or the Medical
19 Practice Act, Chapter 5 (commencing with Section 2000) of
20 Division 2.

21 (d) Permitting a licensed trainee to perform tests or procure
22 specimens unless under the direct and responsible supervision of
23 a person duly licensed under this chapter or physician and
24 surgeon other than another licensed trainee.

25 (e) Violation of any provision of this code governing the
26 practice of medicine and surgery.

27 (f) Proof that an applicant, licensee, or registrant has made
28 false statements in any material regard on the application for a
29 license, registration, or renewal issued under this chapter.

30 (g) Conduct inimical to the public health, morals, welfare, or
31 safety of the people of the State of California in the maintenance
32 or operation of the premises or services for which a license or
33 registration is issued under this chapter.

34 (h) Proof that the applicant or licensee has used any degree, or
35 certificate, as a means of qualifying for licensure that has been
36 purchased or procured by barter or by any unlawful means or
37 obtained from any institution that at the time the degree,
38 certificate, or title was obtained was not recognized or accredited
39 by the department of education of the state where the institution

1 is or was located to give training in the field of study in which
2 the degree, certificate, or title is claimed.

3 (i) Violation of any of the prenatal laws or regulations
4 pertaining thereto in Chapter 2 (commencing with Section
5 120675) of Part 3 of Division 105 of the Health and Safety Code
6 and Article 1 (commencing with Section 1125) of Group 4 of
7 Subchapter 1 of Chapter 2 of Part 1 of Title 17 of the California
8 Code of Regulations.

9 (j) Knowingly accepting an assignment for clinical laboratory
10 tests or specimens from and the rendering of a report thereon to
11 persons not authorized by law to submit those specimens or
12 assignments.

13 (k) Rendering a report on clinical laboratory work actually
14 performed in another clinical laboratory without designating
15 clearly the name and address of the laboratory in which the test
16 was performed.

17 (l) Conviction of a felony or of any misdemeanor involving
18 moral turpitude under the laws of any state or of the United
19 States arising out of or in connection with the practice of clinical
20 laboratory technology. The record of conviction or a certified
21 copy thereof shall be conclusive evidence of that conviction.

22 (m) Unprofessional conduct.

23 (n) The use of drugs or alcoholic beverages to the extent or in
24 a manner as to be dangerous to a person licensed under this
25 chapter, or any other person to the extent that that use impairs the
26 ability of the licensee to conduct with safety to the public the
27 practice of clinical laboratory technology.

28 (o) Misrepresentation in obtaining a license or registration.

29 (p) Performance of, or representation of the laboratory as
30 entitled to perform, a clinical laboratory test or examination or
31 other procedure that is not within the specialties or
32 subspecialties, or category of laboratory procedures authorized
33 by the license or registration.

34 (q) Refusal of a reasonable request of HCFA, a HCFA agent,
35 the department, or any employee, agent or contractor of the
36 department, for permission to inspect, pursuant to this chapter,
37 the laboratory and its operations and pertinent records during the
38 hours the laboratory is in operation.

39 (r) Failure to comply with reasonable requests of the
40 department for any information, work, or materials that the

1 department concludes is necessary to determine the laboratory's
2 continued eligibility for its license or registration, or its
3 continued compliance with this chapter or the regulations
4 adopted under this chapter.

5 (s) Failure to comply with a sanction imposed under Section
6 1310.

7 (t) Failure to comply with the infectious disease reporting
8 requirements specified in Sections 2505, 2552, and 2612 of Title
9 17 of the California Code of Regulations, and other related
10 sections.

11 SEC. 3. No reimbursement is required by this act pursuant to
12 Section 6 of Article XIII B of the California Constitution because
13 the only costs that may be incurred by a local agency or school
14 district will be incurred because this act creates a new crime or
15 infraction, eliminates a crime or infraction, or changes the
16 penalty for a crime or infraction, within the meaning of Section
17 17556 of the Government Code, or changes the definition of a
18 crime within the meaning of Section 6 of Article XIII B of the
19 California Constitution.